510k Submission for

Pan Probe Biotech LiveSure™ Methadone Screen Test Card & Test Strip

Pan Probe Biotech, Inc. NOV 2 6 2001 K013796 Revision B, October 22, 2001

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

The sponsor, Probe Biotech, Inc., has developed, manufactured, and tested under Good Laboratory Practices guidelines, in vitro diagnostic (IVD) devices for qualitative testing of urine samples for the presence of Methadone, its analogs, and metabolites in an IVD screening format. The trade name of the devices are the Pan Probe Biotech LiveSure™ Methadone Screen Test Card and Test Strip, having FDA assigned name: Methadone Test Systems, and a classification as a Class II device per 21 CFR 862.3260, with product code: DJR. These IVD devices are intended for medical/forensic screening of urines for Methadone, its analogs, and metabolites.

The Pan Probe Biotech LiveSure™ Methadone Screen Test Card and Test Strip (i.e., LiveSure™ Methadone) devices are rapid qualitative competitive chromatographic IVD immunoassays, in which chemically labeled drug conjugate competes with any Methadone (MED) drugs, analogs or metabolites that may be present in test urinary samples for limited specific antibody binding sites. LiveSure™ Methadone devices contain a unique membrane that has been pre-coated both with a Methadone (MED-)drug conjugate at the test band, and is followed by a built-in reference band with a second antibody as a system control band. A pink colored anti-MED monoclonal antibody-colloidal gold conjugate pad is placed to the right of a test strip. In the absence of MED drugs, analogs or metabolites in urine, pink colored antibody-colloidal gold conjugates move chromatographically along with the urinary samples on the membrane by capillary action. Antibody-colloidal gold conjugate binds to MED-drug conjugate, forming an antibody-antigen complex. This antibody-MED-drug conjugate appears as second visible pink colored band and captured reagent at the test region. Any MED present in a sample urine act as antigens, competing with MED-drug conjugate at the test band region for limited MED-antibody binding sites on antibody-colloidal gold conjugate. When a sufficient concentration of urinary MED drugs, analogs or metabolites are present, these analytes block the limited antibody binding sites. This blockage-binding process prevents attachment of pink colored antibody-colloidal gold conjugate at the MED-drug conjugate zone located at the test band region. To serve as a procedural control, a pink colored band in a control region will always appear, regardless of the presence of MED in urine samples. Thus, negative urine samples produce two pink colored bands, while positive urine samples produce only one pink colored band.

In-house testing of LiveSure™ Methadone Screen Test Card and Test Strip devices against EMIT® II Methadone Assay as a predicate device provided data essentially showing equivalency between the Card and Strip devices, and to the predicate EMIT® II Assay. Additionally, independent clinical testing of 301 urine samples against LiveSure™ Methadone Screen Test Card and Test Strip devices, as well as EMIT® II Assay at an external reference laboratory resulted in a 100% percent agreement with all GC/MS quantitative positive results. Moreover, LiveSure™ Methadone Test Card or Strip gave both 99.0% agreement with GC/MS negative results. In comparing the Test Card and Test Strip positives with EMIT® II positives, both gave 98.4% respective agreement with EMIT® II positives. Specificity of Test Card and Test Strip negatives with EMIT® II negatives was shown to be 99.4% for both. In terms of overall accuracy of values at and below the ±25% range of the NIDA/SAMHSA cut-off of 300 ng Methadone/ml, however, the LiveSure™ Methadone Screen Test Card and Strip yielded no false positives (FP), whereas EMIT®II resulted in 1 FP value for urine samples with GC/MS results below 225 ng/ml. Also EMIT® II apparently had 1 false negative (1FN), while Test Card & Test Strip gave zero FN results vs. GC/MS. Finally, the LiveSure™ Methadone Test Card and the Test Strip gave overall accuracy results of 299/301 (99.3%) for both versus GC/MS data, whereas 296/301 (98.3%) accuracy was obtained with EMIT®II immunoassay. Thus, the LiveSure™ Methadone Test Card and Test Strip devices were determined to be substantially equivalent in performance to the approved predicate EMIT® II Methadone immunoassay device, and the LiveSure™ Methadone Test Card and Test Strip devices were shown to be substantially equivalent to each other in performance, each versus the external GC/MS Methadone laboratory results.

Additional information on this submission may be obtained by contacting Alice Yu, Vice President, Pan Probe Biotech, Inc. at: 1- 858-689-9936 or by fax at 1-858-689-6896.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 6 2001

Pan Probe Biotech, Inc.
c/o Raymond Wilson, Pharm. D.
California Department of Health Services
Food and Drug Branch
714/744 P Street
P.O. Box 942732 (MS-357)
Sacramento, CA 94234-7320

Re: k013796
Trade/Device Name: PanProbe Biotech, Inc. LiveSure™ Methadone Screen Test Card & Test Strip
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: November 2, 2001
Received: November 15, 2001

Dear Dr. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Regulatory No. (if known): 21 CFR 862.3620; Product Code: DJR

DEVICE NAME: Pan Probe Biotech, Inc. LiveSure™ Methadone Screen Test Card & Test Strip

INDICATIONS FOR USE STATEMENT

The Pan Probe Biotech (PPB), Inc LiveSure™ Methadone Screen Test Card & Test Strip devices are rapid *in vitro* diagnostic (IVD) qualitative lateral flow competitive immuno-chromatographic urinary screening devices intended for detection of Methadone, its analogs and metabolites (collectively termed: **MED**) at the NIDA (National Institute on Drug Abuse) and SAMHSA (Substance Abuse and Mental Health Services Administration) cut-off level of 300 ng MED/ml of human urine. These PPB LiveSure™ Methadone Test Card & Test Strip IVD immunoassay devices are designed for visual, qualitative screening, for professional use only, and are not intended for quantitative results, nor for over-the-counter (OTC) sales. PPB LiveSure™ Methadone Test Card & Test Strip devices provide only preliminary qualitative screening data for use to aid in the diagnosis of drug abuse or over use. A more specific quantitative alternative method must be used in order to obtain a confirmed analytical result. NIDA and SAMHSA have established gas chromatographic/mass spectrometry (GC/MS) as the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013796

✓ Prescription Use _____ Over the Counter Use